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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/098,709	03/13/2002	Peter M. Allred	7678.614	5008

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EXAMINER

MCCLENDON, SANZA L

ART UNIT

PAPER NUMBER

1711

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No.	Applicant(s)	
	10/098,709	ALLRED ET AL.	
	Examiner	Art Unit	
	Sanza L McClendon	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 18-31, 33-40, 43, 45-60 and 62-67 is/are rejected.
- 7) ☒ Claim(s) 15-17, 32, 41, 42, 44, 61, 68 and 69 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-14, 18-31, 33-40, 43, 45-48, 52-54, 55-60, and 62-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitra et al (US 5,922,786) in view of Ario et al (US 5,595,487) and (Fischer et al (5,708,052).

Mitra et al teaches multi-part dental adhesive primer compositions for application in an oral environment such as to amalgam—see column 11, lines 60-62 and abstract. Said compositions comprise in part A of the multi-part system an acid functional (meth) acrylate polymer; a reactive diluent, such as HEMA or BIS-GMA; a solvent, such as ethanol or acetone; a photoinitiator, such as an α -diketone and an accelerator, such as a peroxide; and a hydrophilic compound that comprises (meth) acrylate groups and phosphine groups. Instead of a photoinitiator, part A can comprise a reducing agent/oxidizing agent chemical initiator. Part B comprises an acidic compound, such as acrylic acid or methacrylic acid. In addition, Mitra et al teaches said composition can comprise adjuvants, such as co-solvents, inhibitors, medicament fillers, fluoride releasing compounds and others well-known in the art. Said fluoride releasing agents can be silanated, such as those taught in preparatory example 1. Per preparatory example 4, Mitra et al teaches adding a polymerization

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inhibitor to part A of the primer adhesive system. Said photoinitiator can be added in amounts from 0.01 to about 5% by weight, wherein the examiner contends that the lower limit ranges for the photoinitiator taught by Mitra et al read on the upper limits of applicant's claims 27-29 and the peroxide accelerator reads on claim 30.

Fischer et al teaches primer/sealing dental compositions. Said primer/sealer comprises a mixture of a polymerization initiator, such as camphoroquinone, and a polymerizable promoter, such as methacrylic acid. Said primer may further comprise a solvent, such as ethanol, a natural resin, such as Canadian balsam, and a polymerizable resin such as HEMA. Said polymerization promoter, in addition to methacrylic acid, can comprise compounds of the two formulas found in column 7 and can be found in amounts from 0.05 to 99.95%. Said polymerization initiator can be found in amounts, preferably, from 0.05 to 1% and, also, comprise a redox chemical initiator. Said polymerizable resin can comprise other than HEMA compounds found in column 8 and used in amounts from 0.05 to 95% by weight. Other natural resin besides Canadian balsam can be used, wherein these can be found in columns 9-10 and used in amounts from 0.05 to about 55%. In addition to the above components said primer can comprise a polymerization inhibitor.

Mitra et al and Fischer et al are analogous art because they are from the same field of endeavor that is the art of dental compositions for bonding resinous and non-resinous materials to dental substrates.

Mitra et al does not expressly teach using a photoinitiator in combination with a chemical initiator, however Fisher et al teaches an adhesive composition comprising the same and/or similar components that comprise a photoinitiator system and a chemical redox initiator to ensure a complete cure. Therefore, it would have been obvious for a skilled artisan to use both a photoinitiator system and chemical initiator system. The motivation would have been to ensure a complete cure of a dental restorative in the absence of evidence to the contrary.

Mitra et al does not expressly teach adding chemical promoters having the formula found in claim 6. However, Fischer et al teaches adding chemical promoters

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of the formula found in column 7, which reads on claim 6. Because the composition of Mitra et al and Fischer et al are analogous, it would have been obvious for a skilled artisan to use the chemical promoters as taught Fischer, in addition to or instead of the methacrylic acid as taught by Mitra et al in part B of the primer adhesive composition. The motivation would have been the expectation adequate success in obtaining a primer/adhesive composition because the promoter compounds are analogously/interchangeably uses in the prior art as taught by Fischer et al in the absence of unexpected results.

Mitra et al does not expressly teach adding natural resin to the primer adhesive composition. However Fischer et al teaches adding natural resins in primer composition that are analogous to the adhesive compositions of Mitra et al. Therefore it would have been obvious to add natural resin, as taught by Fischer et al, to the adhesive primer compositions as taught by Mitra et al. The motivation would have been to enhance the bond strength between the substrate coated with said composition and the subsequently applied bonding material in the absence of unexpected results and/or arguments to the contrary.

Ario et al teaches methods of bonding amalgam to dental surfaces. Said method comprises an etching step, a treatment step, applying a primer solution that is copolymerizable with the adhesive of the next step, applying an adhesive to the primed surface, and applying amalgam to the adhesive coated dental surface. Said adhesive comprises a BIS-GMA with a hydrophilic monomer, such as HEMA, hydroxypropyl methacrylate, or methacrylic acid, acrylate or methacrylate functional polymers and phosphorous containing compounds, reactive diluents, such as HEMA, methyl methacrylate, and others in column 10. Optionally, said adhesive can comprise polymers used in the primer compositions. In addition, the adhesive can comprise conventional fillers and adjuvants used in primer compositions. Ario et al teaches said adhesive composition can comprise chemical initiators, such as peroxide, such as benzoyl peroxide, and a reducing agent. Additionally, the adhesive can comprise a photoinitiator—see column 9, lines 11-67 to column 10, and lines 1-17. Ario et al

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teaches the adhesive is applied to the primed dental surface after initiation of the polymerization reaction in an amount effective to bond the amalgam to the dental surface. Said amalgam is applied to the surface of adhesive coated surface before the dental adhesive is fully cured to give a dental practitioner sufficient working time after application of the redox curable adhesive in which to place the amalgam before full curing of the adhesive takes place.

Mitra et al and Ario et al are analogous art because they are from the same field of endeavor that is the use of polymerizable systems to bond amalgam to dental substrates.

Mitra et al does not expressly teach adding a photoinitiator system in an amount effective so that at least portion of the polymerizable material in the adhesive remains at least partially unpolymerized when exposed to radiant energy sufficient to initiate polymerization of said adhesive and adding at least one chemical initiator that causes further polymerization of the adhesive material when in contact with an amalgam restorative. However, Ario et al teaches the adhesive is applied to the primed dental surface after initiation of the polymerization reaction in an amount effective to bond the amalgam to the dental surface, wherein said amalgam is applied to the surface of adhesive coated surface before the dental adhesive is fully cured to give a dental practitioner sufficient working time after application of the redox curable adhesive in which to place the amalgam before full curing of the adhesive takes place. Therefore, it would have been obvious to add the photoinitiator in an amount effective to leave at least a portion of an adhesive unpolymerized when exposed to radiant energy. The motivation would have been to allow a dental practitioner sufficient working time after application of a redox/radiation curable adhesive in which to place the amalgam before full curing of the adhesive takes place in the absence of evidence to the contrary or unexpected results.

In summary, the combination of references applied in the above rejection is deemed to render applicant's invention obvious in view of the prior art. Mitra et

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al teaches primer adhesives useful for bonding to amalgam comprising polymerizable resins, acid compounds, photoinitiators, reactive diluents, optional hydrophilic phosphine containing resins and/or compounds, and solvents in a two-part system. Fischer et al teaches a similar primer composition that additionally comprises natural resins, chemical initiators, and polymerization inhibitors in stable one-part compositions. Because the compositions of Mitra et al and Fischer et al are analogous, it would have been obvious to a skilled artisan to provide either a two-part or one-part adhesive system for bonding amalgam to dental substrates. The motivation would have been to provide dental practitioners with a choice of adhesive systems to offer to a dental patient in the absence of evidence to the contrary. Ario et al teaches partially curing a primed adhesive before the application of amalgam to allow a dental practitioner sufficient working time with the amalgam before fully curing said primed adhesive. Therefore, it would have been obvious to a skilled artisan to produce a polymerizable dental composition comprising at least on polymerizable resin, photoinitiator, and chemical initiator, wherein the photoinitiator is in an effective amount to partially polymerize the compositions with radiation and the chemical initiator allows for polymerization when in contact with the amalgam restorative material in the absence of unexpected results. The motivation would have been to allow a dental practitioner sufficient working time after application of a redox/radiation curable adhesive in which to place the amalgam before full curing of the adhesive takes place in the absence of evidence to the contrary or unexpected results. In addition, it is deemed that claim 67 is rendered obvious by the combination when the BIS-GMA is 0% by weight for the reasons detailed above.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 11-14, 18, 20-24, 27-30, 39-40, 43, 45-51, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitra et al (5,922,786).

Mitra et al teaches multi-part dental adhesive primer compositions for application in an oral environment such as to amalgam—see column 11, lines 60-62 and abstract. Said compositions comprise in part A of the multi-part system an acid functional (meth) acrylate polymer; a reactive diluent, such as HEMA or BIS-GMA; a solvent, such as ethanol or acetone; a photoinitiator, such as an α -diketone (camphoroquinone) and an accelerator, such as a peroxide; and a hydrophilic compound that comprises (meth) acrylate groups and phosphine groups. Instead of a photoinitiator, part A can comprise a reducing agent/oxidizing agent chemical initiator. Part B comprises an acidic compound, such as acrylic acid or methacrylic acid. In addition, Mitra et al teaches said composition can comprise adjuvants, such as co-solvents, inhibitors, medicament fillers, fluoride releasing compounds and others well-known in the art. Said fluoride releasing agents can be silanated, such as those taught in preparatory example 1. Per preparatory example 4, Mitra et al teaches adding a polymerization inhibitor to part A of the primer adhesive system. Said photoinitiator can be added in amounts from 0.01 to about 5% by weight, wherein the examiner contends that the lower limit ranges for the photoinitiator taught by Mitra et al read on the upper limits of applicant's claims 27-29 and the peroxide accelerator reads on claim 30.

Because Mitra et al anticipates claims 1-5, 11-14, 18, 20-24, 27-30, 39-40, 43, 45-48, and 53, the final bonding strengths found in claims 49-51 should be inherent to the cured compositions in the absence of evidence to the contrary.

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Allowable Subject Matter

5. Claims 15-17, 32, 41-42, 44, 61, and 68-69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to teach adding the low amounts of BIS-GMA resin in dental adhesive and/or primer compositions for bonding amalgam to dental substrates.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanza L McClendon whose telephone number is (703) 305-0505. The examiner can normally be reached on Monday through Friday 8:00 to 4:30.

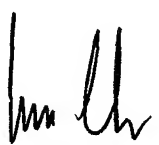
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (703) 308-2462. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0657.

Sanza L McClendon

Examiner

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James Seidleck
Supervisory Patent Examiner
Technology Center 1700

SMc